UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 18, 2006

MEMORANDUM

Subject: Efficacy Review for Benefect® Botanical Daily Cleaner Disinfectant Spray, EPA File Symbol 74771-G; DP Barcode: D325395

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Applicant: Sensible Life Products
34-7 Innovation Dr.
Flamborough, Ontario, Canada L9H 7H9

Formulation from the Label:

Active Ingredient(s)	% by wt.
Thymol (present as acomponent of Thyme Oil)	0.05 %
Inert Ingredients	99.95 %
Total	100.00 %

I. BACKGROUND

The product, Benefect® Botanical Daily Cleaner Disinfectant (EPA File Symbol 74771-G), is a new product. The applicant requested to register the product as a disinfectant (bactericide, virucide) for use on hard, non-porous surfaces in household, institutional, food preparation, commercial, animal care, and hospital or medical environments. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated January 5, 2006), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), eleven studies (MRID Nos. 467246-04 through 467246-14), Statements of No Data Confidentiality Claims for all 11 studies, and the proposed label.

Note: EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Data or information claimed by the applicant to be FIFRA confidential has not been included in this report.

Note: The laboratory reports describe studies conducted for the products, JS-11 and D109. The applicant's representative has explained that the product, JS-11, is the basic formulation, Benefect® Botanical Daily Cleaner Disinfectant, and that the product, D109, is the alternate formulation, Benefect® Botanical Weekly Cleaner Disinfectant.

II. USE DIRECTIONS

The product is designed for use in disinfecting hard, non-porous surfaces such as appliances, bathtubs, changing tables, counter tops, cribs, floors, furniture, garbage cans, helmets, highchairs, mirrors, prostheses and orthotics, seating, showers, sinks, stovetops, tabletops, toilets, toys, vanities, walls, and windows. The label claims that the product may be used on hard, non-porous surfaces such as tile and grout. Directions on the proposed label provided the following information regarding use of the product:

> As a disinfectant – Wet the surface. Leave for 10 minutes. Allow to air dry. No rinsing or wiping is required.
>
> To control mold and mildew odors – Wet the surface. Leave for 3 minutes. Wipe clean. Reapply as necessary.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least

60 days old, against *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants", killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. These Agency standards are presented in DIS/TSS-1.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step. These Agency standards are also presented in DIS/TSS-1.

Disinfectants for Use in Hospital or Medical Environments; Confirmatory Efficacy Data Requirements: Under certain circumstances, an applicant is permitted to rely on previously submitted efficacy data to support an application or amendment for registration of a product and to submit only minimal confirmatory efficacy data on his own product to demonstrate his ability to produce an effective formation. This includes a minor formulation change (e.g., a change in an inert ingredient) in a registered product. Confirmatory data must be developed on the applicant's own finished product. For hospital disinfectants, 10 carriers on each of 2 samples representing 2 different product lots must be tested against *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442) using either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. To support products labeled as "disinfectants", Killing on all carriers is required. These Agency standards are presented in DIS/TSS-5.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Products Controlling Microorganisms of Economic or Aesthetic Significance: Algaecides, slimicides, preservatives, deodorizers, and other products expressly claiming control of microorganism of economic or aesthetic significance not directly related to human's health do not require efficacy data. However, adequate dosage recommendations and complete directions for use must be provided in labeling. These Agency standards are presented in DIS/TSS-16.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. This Agency standard is presented in DIS/TSS-2.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 467246-04 "AOAC Germicidal Spray Method, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for JS-11, by David Rottjakob. Study conducted at ATS Labs. Study completion date – November 7, 2005. Project Number A03352.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Two lots (Lot Nos. 051O1301-2 and 051O1301-3) of the product, JS-11, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed (6 sprays) at a distance of 3-4 inches from the surface, until wet. Each carrier was exposed to the product for 10 minutes at 21°C at 24% relative humidity. Following the exposure period, the remaining liquid was drained off. Individual carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. For the dried colony counts, carrier/neutralizing broth mixtures were vortex mixed. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average colony forming units per carrier, for the test microorganism, is ***Staphylococcus aureus* 1.17 x 10^6**.

2. MRID 467246-05 "AOAC Germicidal Spray Method, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for JS-11, by David Rottjakob. Study conducted at ATS Labs. Study completion date – December 5, 2005. Project Number A03412.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One lot (Lot No. 051S1201-3) of the product, JS-11, was tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product lot tested was at least 60 days old at the time of testing. The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried

for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed (10 sprays) at a distance of 3-4 inches from the surface. Each carrier was exposed to the product for 10 minutes at 20°C at 14% relative humidity. Following the exposure period, the remaining liquid was drained off. Individual carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. For the dried colony counts, carrier/neutralizing broth mixtures were vortex mixed. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average colony forming units per carrier, for the test microorganism, is ***Staphylococcus aureus*** **9.6 x 10^5**.

3. MRID 467246-06 "AOAC Germicidal Spray Method, Test Organism: *Salmonella choleraesuis* (ATCC 10708)" for Benefect Disinfectant JS-11, by David Rottjakob. Study conducted at ATS Labs. Study completion date – October 31, 2005. Project Number A03264.

This study was conducted against *Salmonella choleraesuis* (ATCC 10708). Three lots (Lot Nos. 051S1201-1, 051S1201-2, and 053J1102-1) of the product, Benefect Disinfectant JS-11, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. At least one of the product lots tested (Lot No. 053J1102-1) was at least 60 days old at the time of testing. The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed (10 sprays) at a distance of 3-4 inches from the surface. Each carrier was exposed to the product for 5 minutes at 22°C at 22% relative humidity. Following the exposure period, the remaining liquid was drained off. Individual carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then stored at 2-8°C for 1 day. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average colony forming units per carrier, for the test microorganism, is ***Salmonella choleraesuis*** **1.6 x 10^4**

4. MRID 467246-07 "AOAC Germicidal Spray Method, Test Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for Benefect JS-11, by David Rottjakob. Study conducted at ATS Labs. Study completion date – September 16, 2005. Project Number A03092.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. 053J1102-2, 053J1102-3, and 052M0602-3) of the product, Benefect JS-11, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. At least one of the product lots tested (Lot No. 052M0602-3) was at least 60 days old at the time of testing. The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity.

For each lot of product, separate carriers were sprayed (10 sprays) at a distance of 3-4 inches from the surface. Each carrier was exposed to the product for 5 minutes at 19°C at 44% relative humidity. Following the exposure period, the remaining liquid was drained off. Individual carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average colony forming units per carrier, for the test microorganism, is ***Pseudomonas aeruginosa* 1.48 x 10^6**

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

5. MRID 467246-08 "AOAC Germicidal Spray Method, Test Organism: *Escherichia coli* (ATCC 11229)" for Benefect JS-11, by David Rottjakob. Study conducted at ATS Labs. Study completion date – September 21, 2005. Project Number A03095.

This study was conducted against *Escherichia coli* (ATCC 11229). Two lots (Lot Nos. 053J1102-2 and 053J1102-3) of the product, Benefect JS-11, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed (10 sprays) at a distance of 3-4 inches from the surface. Each carrier was exposed to the product for 5 minutes at 23°C at 50% relative humidity. Following the exposure period, the remaining liquid was drained off. Individual carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average colony forming units per carrier, for the test microorganism, is ***Escherichia coli* 5.1 x 10^5**

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

6. MRID 467246-09 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A virus" for Benefect JS-11, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – August 12, 2005. Project Number A03091.

This study was conducted against Influenza A virus (ATCC VR-544; Strain Hong Kong), using Rhesus monkey kidney cells (obtained from ViroMed Laboratories, Inc.) as the host system. Two lots (Lot Nos. 053J1102-2 and 053J1102-3) of the product, Benefect JS-11, were tested according to ATS Labs Protocol No. SLP02051005.FLUA (copy not provided). The product was received ready-to-use. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C at 48% relative

humidity for 20 minutes. For each lot of product, separate dried virus films were sprayed (10 sprays) with the product at a distance of 3-4 inches from the surface. Each virus film was exposed to the product for 5 minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. Rhesus monkey kidney cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus counts, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **7.0 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reductions in viral titer were **5.5 $\log_{10}$** and **6.5 $\log_{10}$** for the batches.

7. MRID 467246-10 "AOAC Germicidal Spray Method, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for D109, by David Rottjakob. Study conducted at ATS Labs. Study completion date – September 19, 2005. Project Number A03187.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Two lots (Lot Nos. 052J1102(b)-1 and 052J1102(b)-3) of the product, D109, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed (10 sprays) at a distance of 3-4 inches from the surface. Each carrier was exposed to the product for 10 minutes at 21°C at 46% relative humidity. Following the exposure period, the remaining liquid was drained off. Individual carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average colony forming units per carrier, for the test microorganism, is ***Staphylococcus aureus* 96 x 10^5**

8. MRID 467246-11 "AOAC Germicidal Spray Method, Test Organism: *Salmonella choleraesuis* (ATCC 10708)" for D109, by David Rottjakob. Study conducted at ATS Labs. Study completion date – October 3, 2005. Project Number A03237.

This study was conducted against *Salmonella choleraesuis* (ATCC 10708). Two lots (Lot Nos. 052J1102(b)-1 and 052J1102(b)-3) of the product, D109, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 32 minutes at 35-37°C at 40% relative

humidity. For each lot of product, separate carriers were sprayed (10 sprays) at a distance of 3-4 inches from the surface. Each carrier was exposed to the product for 5 minutes at 22°C at 52% relative humidity. Following the exposure period, the remaining liquid was drained off. Individual carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 44 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average colony forming units per carrier, for the test microorganism, is ***Salmonella choleraesuis* 1.7 x 10^4**

9. MRID 467246-12 "AOAC Germicidal Spray Method, Test Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for D109, by David Rottjakob. Study conducted at ATS Labs. Study completion date – October 28, 2005. Project Number A03236.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Two lots (Lot Nos. 052J1102(b)-1 and 052J1102(b)-3) of the product, D109, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use. Testing was conducted on September 12, 2005 and October 4, 2005. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed (10 sprays) at a distance of 3-4 inches from the surface. Each carrier was exposed to the product for 5 minutes at 21°C at 51% relative humidity. Following the exposure period, the remaining liquid was drained off. Individual carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average colony forming units per carrier, for the test microorganism, is ***Pseudomonas aeruginosa* 9.5 x 10^5**

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: Repeat testing (i.e., Lot No. 052J1102(b)-1) was conducted on October 4, 2005 to evaluate for false positives.

10. MRID 467246-13 "AOAC Germicidal Spray Method, Test Organism: *Escherichia coli* (ATCC 11229)" for D109, by David Rottjakob. Study conducted at ATS Labs. Study completion date – September 28, 2005. Project Number A03235.

This study was conducted against *Escherichia coli* (ATCC 11229). Two lots (Lot Nos. 052J1102(b)-1 and 052J1102(b)-3) of the product, D109, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative

humidity. For each lot of product, separate carriers were sprayed (10 sprays) at a distance of 3-4 inches from the surface. Each carrier was exposed to the product for 5 minutes at 22°C at 52% relative humidity. Following the exposure period, the remaining liquid was drained off. The carriers were transferred to 20 ml of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average colony forming units per carrier, for the test microorganism, is ***Escherichia coli* 3.4 x 10^5**

11. MRID 467246-14 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A virus" for D109, by Mary Miller. Study conducted at ATS Labs. Study completion date – October 3, 2005. Project Number A03252.

This study was conducted against Influenza A virus (ATCC VR-544; Strain Hong Kong), using Rhesus monkey kidney cells (obtained from ViroMed Laboratories, Inc.) as the host system. Two lots (Lot Nos. 052J1102(b)-1 and 052J1102(b)-3) of the product, D109, were tested according to ATS Labs Protocol No. SLP02081105.FLUA (copy not provided). The product was received ready-to-use. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 19.5°C at 42% relative humidity for 20 minutes. For each lot of product, separate dried virus films were sprayed (10 sprays) with the product at a distance of 3-4 inches from the surface. Each virus film was exposed to the product for 5 minutes at 19.5°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. Rhesus monkey kidney cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus counts, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **7.25 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **5.75 $\log_{10}$** for both batches.

V. RESULTS

A. Test Results for Basic Formulation of the Product

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Population (CFU/ carrier)
		Lot No. 051O1301-2	Lot No. 051O1301-3	Lot No. 051S1201-3	
467246-04	*S. aureus*	0/60	0/60	---	1.17×10^6
467246-05	*S. aureus*	--	--	0/60	9.6×10^5
		Lot No. 051S1201-1	**Lot No. 051S1201-2**	**Lot No. 053J1102-1**	
467246-06	**S. choleraesuis**	0/60	0/60	0/60	1.6×10^4
		Lot No. 053J1102-2	**Lot No. 053J1102-3**	**Lot No. 052M0602-3**	
467246-07	*P. aeruginosa*	0/60	0/60	0/60	1.48×10^6
467246-08	*E. coli*	0/10	0/10	---	5.1×10^5

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1 ml)
			Lot No. 053J1102-2	Lot No. 053J1102-3	
467246-09	Influenza A virus	10^{-1} dilution	Cytotoxicity	Complete inactivation	$10^{7.0}$
		10^{-2} to 10^{-9} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/0.1 ml	$10^{1.5}$	$10^{0.5}$	
		Log reduction	$\geq 5.5 \log_{10}$	$\geq 6.5 \log_{10}$	

B. Test Results for Alternate Formulation of the Product

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Population (CFU/carrier)
		Lot No. 052J1102(b)-1	Lot No. 052J1102(b)-3	
467246-10	*S. aureus*	0/10	0/10	9.6×10^5
467246-11	S. choleraesuis	0/10	0/10	1.7×10^4
467246-12	*P. aeruginosa* Test Date: 09/12/05 Test Date: 10/04/05	 1/10 0/10	 0/10 --	 1.15×10^6 9.5×10^5
467246-13	*E. coli*	0/10	0/10	3.4×10^5

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1 ml)
			Lot No. 052J1102(b)-1	Lot No. 052J1102(b)-3	
467246-14	Influenza A virus	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{7.25}$
		10^{-2} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/0.1 ml	$10^{1.5}$	$10^{1.5}$	
		Log reduction	$\geq$ 5.75 log_{10}	$\geq$ 5.75 log_{10}	

VI. CONCLUSIONS

A. Conclusions Regarding Basic Formulation of the Product

1. The submitted efficacy data **support** the use of the product, JS-11, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for the contact time listed:

Staphylococcus aureus	10 minutes	MRID Nos. 467246-04 and 467246-05
Salmonella choleraesuis	5 minutes	MRID No. 467246-06
Pseudomonas aeruginosa	5 minutes	MRID No. 467246-07
Escherichia coli	5 minutes	MRID No. 467246-08

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. In studies against *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, and *Staphylococcus aureus*, at least one of the product lots tested was at least 60 days old at the time of testing. Carrier population counts were at least 10^4. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data (MRID No. 467246-09) **support** the use of the product, JS-11, as a disinfectant with virucidal activity against the **Influenza A virus** on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 5 minutes. A recoverable virus titer of at least 10^4 was achieved. Cytotoxicity was observed in the 10^{-1} dilution (for one product lot). Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

B. Conclusions Regarding Alternate Formulation of the Product

1. The submitted confirmatory efficacy data support the use of the product, D109, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for the contact time listed:

Staphylococcus aureus	10 minutes	MRID No. 467246-10
Salmonella choleraesius	5 minutes	MRID No. 467246-11

Pseudomonas aeruginosa	5 minutes	MRID No. 467246-12
Escherichia coli	5 minutes	MRID No. 467246-13

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. [Note that repeat testing was conducted against *Pseudomonas aeruginosa* on one product lot. Repeat testing showed acceptable killing.] Carrier population counts were at least 10^4. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data (MRID No. 467246-14) **support** the use of the product, D109, as a disinfectant with virucidal activity against the **Influenza A virus** on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 5 minutes. A recoverable virus titer of at least 10^4 was achieved. Cytotoxicity was observed in the 10^{-1} dilutions. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

VII. RECOMMENDATIONS

1. EPA Form 8570-1 (Application for Pesticide) and EPA Form 8570-35 (Data Matrix) identify the product as Benefect® Botanical Daily Cleaner Disinfectant **Spray**. The product label, EPA Form 8570-4 (Confidential Statement of Formula), and EPA Form 8570-34 (Certification with Respect to Citation of Data) identify the product as Benefect® Botanical Daily Cleaner Disinfectant. The Agency is tracking this product as Benefect® Botanical Daily Cleaner Disinfectant **Spray**. The applicant must revise the paperwork associated with this product so that the product name is consistent.

2. The proposed label claims that the product, Benefect® Botanical [Daily][Weekly] Cleaner Disinfectant, is an effective "one step" disinfectant against the following microorganisms on hard, non-porous surfaces for a contact time of 10 minutes:

Pseudomonas aeruginosa
Salmonella choleraesuis
Staphylococcus aureus
Escherichia coli
Influenza A virus

Data provided by the applicant for both the basic and alternate formulations of the product support these claims. **The directions to disinfect must be revised to specify that heavily soiled areas must be pre-cleaned prior to treatment**.

3. If the product Benefect® Botanical [Daily][Weekly] Cleaner Disinfectant Spray is a disinfectant for hard, non-porous surfaces, the proposed label should not have "on hard, non-porous, inanimate surfaces" as an optional statement. **The applicant must put on the label (on Front Panel) the statement "for hard, non-porous, inanimate surfaces". All label claims for porous and semi-porous surfaces, must be deleted.**

Pseudomonas aeruginosa	5 minutes	MRID No. 467246-12
Escherichia coli	5 minutes	MRID No. 467246-13

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. [Note that repeat testing was conducted against *Pseudomonas aeruginosa* on one product lot. Repeat testing showed acceptable killing.] Carrier population counts were at least 10^4. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data (MRID No. 467246-14) **support** the use of the product, D109, as a disinfectant with virucidal activity against the **Influenza A virus** on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 5 minutes. A recoverable virus titer of at least 10^4 was achieved. Cytotoxicity was observed in the 10^{-1} dilutions. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

VII. RECOMMENDATIONS

1. EPA Form 8570-1 (Application for Pesticide) and EPA Form 8570-35 (Data Matrix) identify the product as Benefect® Botanical Daily Cleaner Disinfectant **Spray**. The product label, EPA Form 8570-4 (Confidential Statement of Formula), and EPA Form 8570-34 (Certification with Respect to Citation of Data) identify the product as Benefect® Botanical Daily Cleaner Disinfectant. The Agency is tracking this product as Benefect® Botanical Daily Cleaner Disinfectant **Spray**. The applicant must revise the paperwork associated with this product so that the product name is consistent.

2. The proposed label claims that the product, Benefect® Botanical [Daily][Weekly] Cleaner Disinfectant, is an effective "one step" disinfectant against the following microorganisms on hard, non-porous surfaces for a contact time of 10 minutes:

Pseudomonas aeruginosa
*Salmonella choleraesuis***
Staphylococcus aureus
Escherichia coli
Influenza A virus

****Please note:** The species name of this organism has been changed by ATTC. The new designation of this organism is *Salmonella* ***enterica.*** This change is effective Immediately, and should be used for all subsequent references to this organisms in the future.

Data provided by the applicant for both the basic and alternate formulations of the product support these claims. **The directions to disinfect must be revised to specify that heavily soiled areas must be pre-cleaned prior to treatment**.

3. If the product Benefect® Botanical [Daily][Weekly] Cleaner Disinfectant Spray is a disinfectant for hard, non-porous surfaces, the proposed label should not have "on hard, non-porous, inanimate surfaces" as an optional statement. **The applicant must put on the label (on Front Panel) the statement "for hard, non-porous, inanimate surfaces". All label claims for porous and semi-porous surfaces, must be deleted.**

4. The product label [see page 1 of the proposed label] claims that the product may be used as a foam on a monthly basis. The applicant has **not** provided efficacy data for a foam-version of the product. **References to use of the product as a foam and on a monthly basis must be deleted from the label**.

5. The proposed label indicates that the product may be used on grout [see page 3 of the proposed label], which is a porous surface. **All references to grout must be deleted from the proposed label**.

6. The proposed label includes **claims that are misleading**. **The following claims must be removed from the proposed label:**

- On page 2, "Benefect® is the first [& only] botanical disinfectant cleaner." The applicant has received EPA approval for another product, Benefect® Botanical Disinfectant (EPA Reg. 74771-1); therefore, the product, Benefect® Botanical Daily Cleaner Disinfectant, is not the "first & only."

- On page 2, "Benefect® with Ingenium cuts the dirt in your life and the clutter under your sink."

- All claims for porous and semi-porous surfaces.

7. On pages 3 and 4 of the proposed label, **the brackets from the following text must be deleted:**

- The areas where the product is recommended for use (i.e., [SUITABLE FOR use in residential . . .])

- The types of surfaces on which the product may be used (i.e., [SUITABLE FOR use on countertops . . .])

- The directions for use.

DIS/TSS-15 requires that this information be included on the product label; this information is not optional.

8. The applicant must make the following changes to the proposed label, as appropriate:

- On page 1, place the signal word, **CAUTION**, below the "Keep Out of Reach of Children" statement. Check that the type size of the "Keep Out of Reach of Children" statement is adequate. Please also delete "[**Common Sense**]" from the proposed label.

- On page 2, change "[and we hope you will too.]" to read "[and we hope you will **be** too.]"

- On page 2, change "[No ammonia, phosphates, **acids** or chlorine bleach.]" to read "[No ammonia, phosphates, or chlorine bleach.]"

- On page 3, change "[....countertops, tiles....]" to read "[....countertops, **glazed** tiles....]"

- Under the "Directions for Use" section [see page 4 of the proposed label], change "with it's **labelling**" to read "with its **labeling**."

- The proposed label includes a TerraChoice logo on page 4. Information demonstrating that the product has received this certification was not provided.

- On page 4 of the proposed label [left column; last paragraph], change "sanitize and **disinfectant**" to read "sanitize and **disinfect**."

- On pages 4 and 6 of the proposed label, change "**moonwalk**" to read "**moonwalks**" and change "obstacle coarse play" to read "obstacle course play."

- Under the "Cleansing of Body Surfaces . . ." section [see page 6 of the proposed label], change "**Bath** the entire body" to read "**Bathe** the entire body."

- Under the "Ultrasonic Bath Disinfectant Directions" [see pages 6-7 of the proposed label], change "**visible** dirty" to read, "**visibly** dirty."